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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,570	12/05/2003	Frank Bergmann	21545-US1	2111

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EXAMINER	
EPPS FORD, JANET L	
ART UNIT	**PAPER NUMBER**
1633	
MAIL DATE	**DELIVERY MODE**
05/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,570	BERGMANN ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 24-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 24-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-06-07 has been entered.

3. It is noted that Applicant's have removed the term "phosphite" in two positions in part (c) of Claim 24, however there are no markings to indicate this change. Applicant's amendment therefore does not comply with 37 CFR 1.121(c).

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-20, and 24-31 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to Applicant's amendment.

5. Applicant's arguments with respect to the rejection of claims 9-20 and 24-31 under 35 U.S.C. 112, second paragraph, have been considered but are moot in view of the new ground(s) of rejection.

6. Claims 9-20 and 24-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 9, and those claims dependent therefrom (claims 10-20 and 24-31) recite the following: “with the proviso that when one residue selected from the group consisting of R5, R6, *or* R7 is a solid phase when the other residues selected from the group consisting of R5, R6, *or* R7 are not a solid phase.” Claim 9 appears to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. The metes and bounds of this Markush group are indefinite because it is unclear if the members of this group are mutually exclusive. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). In the instant case the claim recites a Markush group having the following form: selected from the group consisting of A, B, or C. This form is unclear if the group includes A, B, and C, or if the group includes only one of A, B or C.

8. Claim 24 recites the term “hosphate” in part (c) of this claim. The metes and bounds of this term are vague and indefinite.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheng-Hui et al. (WO 97/43451 A1; See IDS) in view of De Clerq et al. (previously cited) and Alexander et al. (previously cited). *(It is noted that although claims 9-20 are rejected under 112, 2nd as set forth above, the prior art is applied to the extent that R5, R6, and R7 are not all limited to a solid phase).

11. Sheng-Hui et al. describes the following oligomeric compounds, of the following formula (see page 5):

$$R^1 - X - C - CR^2 - C - R^3$$

wherein

R^1 is selected from the group consisting of hydrogen, acid-sensitive, base-stable blocking groups and acyl capping groups;

X is selected from the group consisting of O, S, NH and N=N;

R^2 is a substituent group of the formula

$$X^1 - X^2 - X^3$$

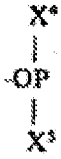
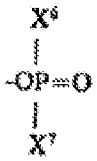
wherein

X^1 is a substituted or unsubstituted C_5 to C_7 cyclic moiety incorporating the carbon atom of the formula;

X^2 is selected from the group consisting of O, S, CH_2, NH and N=N; and

X^3 is hydrogen, or a linking functional group which is capable of linking with a functional moiety; and

R^3 is a linking group of the formula

(a)  or (b) 

wherein

X^4 is halogen or substituted amino,

X^5 is alkyl, alkoxy or phenoxy, or a cyano derivative thereof,

X^6 is halogen, amino or O, and

X^7 is alkyl, alkoxy or aryloxy, or may be H only if X^6 is O, or

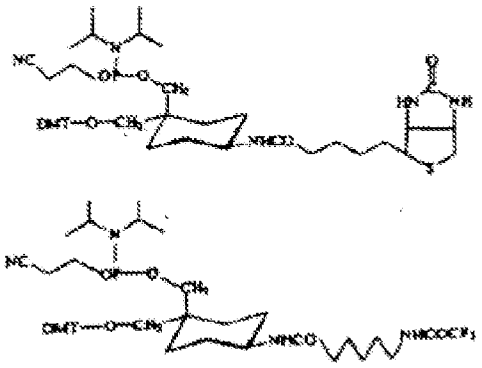
R^3 is a bond, either directly or through an intermediate group, to a solid support.

In the bridging ¶ of pages 7-8, it states that the rigidity of the chemical structure of X^1 provides the desirable feature of extending the linkage group and functional moiety away from the oligomeric backbone structure, thereby substantially enhancing the coupling efficiency of the reagents of their disclosed invention, wherein X^1 is a substituted or unsubstituted cyclohexane.

Additionally, at page 8 of this reference, it states that X^2 functions as a linking and modifiable reactive group, wherein commonly X^2 will be NH, see lines 3-6. Furthermore, the reagents of the invention are designed to be included as non-nucleotide monomeric units in a nucleotide oligomer. X^3 may also serve as a linking functional group, and typically have the following formula -CO-$(CH_2)_n$-NH-functional moiety. The functional moieties of this invention include but are not limited to the following list take from page 7 of this reference (fluorescein mentioned on page 34):

detectable labels (including enzymatic, fluorogenic, radioactive, chemiluminescent, and the like), intercalating agents, metal chelators, drugs, hormones, proteins, peptides, radical generators, nucleolytic agents, proteolytic agents, catalysts, specific binding agents (including biotin, antigens, haptens, antibodies, receptors,

Compounds 1-2 of this reference have the following structure (pp.14, 18):



These compounds are analogous to the compounds of the present invention except that the compounds of the present invention comprise derivatives of 1,5-anhydro-glucitol or 1,-anhydro-mannitol moieties in the position of the X1 moiety recited in the above formula of the oligomeric compounds of Sheng-Hui et al. The compounds of Sheng-Hui

et al. are disclosed as useful for labeling oligomeric compounds used in hybridization of nucleic acids, see page 32.

De Clerq et al. disclose 1,5-anhydrohexitol nucleoside analogues of the following formula:

The present invention relates to 1,5-anhydrohexitol nucleoside analogues, wherein a 4-substituted-2,3,4-tri-deoxy-1,5-anhydrohexitol is coupled via its 2-position to the heterocyclic ring of a pyrimidine or purine base. They are represented by the formula I:

(I)

wherein B is a heterocyclic ring which is derived from a pyrimidine or purine base, and

wherein X represents a hydrogen atom, azido, F, Cl, Br, I, amino —NHR^3, —$N(R^3)_2$, —OR^3, —SR^3 or CN, wherein R^1 and R^3 are the same or different and represent hydrogen, alkyl, acyl or phosphate groups;

The above structure meets all the limitations of the structure of formula I of the instant application except the above structure does not clearly set forth the -NH-[X]n-R^1 moiety that extends from the C2 carbon of the claimed structure. The nucleoside analogues of De Clerq et al. comprise a B moiety, or a heterocyclic ring derived from a pyrimidine or purine base, at the C2 position. As previously stated in a prior art rejection, Alexander et al. clearly contemplate the modification of oligomeric structures with 1,5 anhydrohexitol sugars, particularly as labeling reagents.

It would have been obvious to the ordinary skilled artisan to modify the reagents of Sheng-Hui et al. with the substituted cyclohexene compounds of De Clerq et al. in the design of the instant invention. The ordinary skilled artisan would have been motivated to make this modification since Sheng-Hui et al. expressly teach that X^1 in the formula

of their disclosed reagents preferably are substituted cyclohexane compounds. See MPEP § 2144.06, which recites: "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633

JLE